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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

RANDALL SMITH — PLAINTIFF

VS. — CAUSE NO. _____

MEDTRONIC MINIMED, INC.,
MINIMED DISTRIBUTION CORP.,
MEDTRONIC, INC., MEDTRONIC USA,
INC. & JOHN DOE DEFENDANTS 1-5 — DEFENDANTS

COMPLAINT

JURY TRIAL DEMANDED

COMES NOW the Plaintiff, Randall Smith, through undersigned counsel, and hereby files this Complaint against the Defendants, Medtronic MiniMed, Inc., MiniMed Distribution Corp., Medtronic, Inc., and Medtronic USA, Inc. (hereinafter sometimes collectively referred to as "Defendants" or "Medtronic") and John Doe Defendants 1-5, and the Plaintiff states as follows:

PARTIES

1. Plaintiff, Randall Smith, is an adult resident citizen of Jefferson County, Alabama. His principal residence is located at 3325 Willis Drive, Vestavia Hills, Alabama 35243.

2. Defendant Medtronic MiniMed, Inc., is a foreign corporation organized and existing under the laws of Delaware, with its principal place of business at 18000 Devonshire Street, Northridge, California 91325. At all times relevant this this Complaint, this Defendant conducted business in the State of Alabama, but does not maintain a registered agent for service

of process in Alabama. This Defendant may be served with process upon its registered agent, CT Corporation System, 818 West 7th Street, Los Angeles, California 90017.

3. Defendant MiniMed Distribution Corp., is a foreign corporation organized and existing under the laws of Delaware, with its principal place of business at 18000 Devonshire Street, Northridge, California 91325. At all times relevant this this Complaint, this Defendant conducted business in the State of Alabama. This Defendant may be served with process via service upon its registered agent, Corporation Service Company, Inc., 641 South Lawrence Street, Montgomery, Alabama 36104.

4. Defendant Medtronic, Inc., is a foreign corporation organized and existing under the laws of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. At all times relevant this this Complaint, this Defendant conducted business in the State of Alabama. This Defendant may be served with process via service upon its registered agent, Corporation Service Company, Inc., 641 South Lawrence Street, Montgomery, Alabama 36104.

5. Defendant Medtronic USA, Inc., is a foreign corporation organized and existing under the laws of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. At all times relevant this this Complaint, this Defendant conducted business in the State of Alabama. This Defendant may be served with process via service upon its registered agent, Corporation Service Company, Inc., 641 South Lawrence Street, Montgomery, Alabama 36104.

JURISDICTION AND VENUE

6. This Court has personal jurisdiction over Medtronic because Medtronic regularly conducts business in Alabama and has sufficient minimum contacts in Alabama. Medtronic intentionally availed itself of this jurisdiction by marketing and selling products and services and by accepting and processing payments for those products and services within Alabama. Defendant further availed itself of jurisdiction in Alabama by designing, manufacturing, testing, packaging, marketing, distributing, labeling and/or placing said products in the stream of commerce with the knowledge that said products would reach Alabama.

7. This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interests and costs, and this case is between citizens of different states.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events, acts, and omissions giving rise to Plaintiff's claims occurred in this district and/or because Medtronic is subject to this Court's jurisdiction with respect to this action.

9. The Plaintiff was injured as a result of the defective Medtronic products at issue in this Complaint. The product failures and the proximately resulting injury occurred while he was in Alabama, within the jurisdiction of the United States District Court for the Northern District of Alabama. Jurisdiction and venue are appropriate in this Court.

STATEMENT OF FACTS

10. On or about December 31, 2016, Randall Smith was a healthy, 58 year old resident of Alabama.

11. Randall Smith is a diabetic, and at the time of subject incident he used a Medtronic insulin pump to deliver the necessary amount of insulin into his blood stream to properly treat his diabetes. Said Medtronic insulin pump stored several days' worth of insulin. The insulin is delivered from the pump to the patient's body through plastic tubes called "infusion sets."

12. Randall Smith used Medtronic MiniMed Quick-Set Infusion Sets to deliver the insulin from the pump to his body.

13. On December 31, 2016, shortly after changing the bolus of insulin in his Medtronic pump, he left his home to go to a friend's house to watch a college football playoff game. While on the way, he blacked out and now has no memory of the events beginning shortly after he left his home. After blacking out, he rear-ended another vehicle and eventually ran off the road, crashing his vehicle, resulting in severe and permanent injuries to Randall Smith.

14. Pursuant to the EMS records from shortly after the crash, Randall Smith's blood sugar was 25, which is severely hypoglycemic.

15. Randall Smith's low blood sugar and loss of consciousness, and subsequent collision and injuries, were the direct result of the insulin pump dumping too much insulin into his blood stream, due to a defect with the infusion set as discussed below. The defect, which ultimately resulted in a product recall, causes dangerous over-delivery of insulin shortly after an infusion set change, as occurred in the present case.

16. As a result of the crash, Randall Smith suffered serious and permanent injuries. He broke his back and suffered multiple fractures in his sternum as well as a herniated lumbar

disc, among other injuries. Smith was hospitalized for over a year, resulting in medical bills totaling many hundreds of thousands of dollars.

17. The Medtronic MiniMed infusion set at issue malfunctioned as a result of a defect that caused fluid to block the infusion set membrane during the priming/fill-tubing process, which prevents the infusion set from working properly and results in over-delivery of insulin.

18. The Medtronic MiniMed infusion set at issue was part of a lot of infusion sets that were subsequently recalled on September 7, 2017, due to the defective condition that injured Randall Smith.

THE PRODUCT

19. The Defendants designed, manufactured, marketed and distributed the MiniMed Quick-Set Infusion Sets, which are marketed to deliver insulin from an insulin pump to a diabetes patient in measured amounts. The MiniMed Quick-Set Infusion Sets consist of a membrane and disposable plastic tubes which transport insulin from the pump to the patient's body.

20. The Medtronic MiniMed Infusion Sets are used in conjunction with an insulin pump to help diabetics regulate their blood sugar by providing a constant source of insulin. They provide an alternative to multiple daily injections of insulin. The pump, about the size of a deck of cards, weighs only a few ounces and can be worn on a belt or kept in a pouch under clothing. The pump connects to flexible plastic tubing that delivers insulin to the body. Users set the pump to give a steady trickle of insulin throughout the day. It can be programmed to release larger doses at meals or at times when blood sugar is too high.

21. Randall Smith had no way of knowing that the MiniMed Quick-Set Infusion Sets that he was using were defective in design, manufacture, and marketing, and that, even when used in conformance with Defendants' instructions, they were prone to deliver incorrect and life-threatening doses of insulin.

THE COMPANY

22. Medtronic is a global healthcare products company, with annual revenue in the billions of dollars. Medtronic touts its leadership in the medical device industry, specifically representing that it has 25 years of continuous leadership in diabetes device solutions that improve patients' lives. Medtronic claims to be passionate about diabetes care, with a highly trusted brand and a proven track record for advancing solutions. This claim is echoed in part of Medtronic's mission statement in which Medtronic vows to "strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

23. In spite of Medtronic's stated mission, Medtronic MiniMed insulin pumps and infusion sets have been the subject of a myriad of problems and defects over the years. For example, in sharp contrast to the virtuous ideals from Medtronic's Website are statements from a June 1, 2009 letter from the United States Food and Drug Administration ("FDA") to William A. Hawkins, Medtronic's president and chief executive officer regarding Medtronic PR Operations Co., the firm where MiniMed insulin pumps are manufactured.

In criticizing Medtronic's manufacturing and reporting processes, the FDA cited Medtronic for:

> Failure to report to FDA no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur ...

24. In contravention of applicable regulations, Medtronic had failed to report an incident involving a MiniMed insulin pump in which "device failure or malfunction may have contributed to or caused the user's hospitalization and the device's malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to occur."

25. The FDA also found fault with the personnel that Medtronic entrusted at its manufacturing facility in Puerto Rico with determining whether a Medtronic device was dangerous. Specifically, the FDA cited Medtronic for:

> Failure to have a person who is qualified to make a medical judgment reasonably conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur, as required by [United States federal law]. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers, under [United States federal law].

26. According to FDA Investigators, this plant had a wide range of problems that included lax testing of products for defects, proper record keeping, and employing someone with insufficient training as a medical expert to determine danger or defects. Said employee

only had a high school diploma with some additional in-house training. In listing these and other violations, the FDA concluded that the problems may be symptomatic of serious problems in Medtronic's manufacturing procedures and its quality controls.

27. None of the cited violations reflect Medtronic's hollow promise to strive "without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity and service."

28. On or about June 29, 2009, these issues led to a Class 1 Recall of many of the Defendants' insulin infusion sets labeled Paradigm Quick-Set Infusion Sets. Said recall included lots manufactured between 2007 and 2009. Approximately three million disposable infusion sets were recalled.

29. Unfortunately, past recalls and problems associated with Medtronic infusion sets did not result in Medtronic designing and marketing safe products for use by Randall Smith.

THE CURRENT RECALL

30. On September 7, 2017, Medtronic issued an "Urgent Medical Device Recall" regarding Medctronic MiniMed Infusion Sets.

31. The Recall Notice states that "Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change." Medtronic further notes that it has received reports of hypoglycemia requiring medical attention related to this issue, which Medtronic concedes can result in "hypoglycemia and in extreme cases, death."

32. The Recall Notice states that this problem is caused by fluid blocking the infusion set membrane during the priming/fill-tubing process, which prevents the infusion set from working properly. The result can be fast delivery of multiple days' worth of insulin.

33. The Recall Notice also announces that Medtronic has an alternate infusion set design, which contains a "new and enhanced membrane material that significantly reduces the risk."

34. Defendants were aware or should have been aware of the defects and risks associated with their products, but proceeded with conscious indifference to the rights, safety and welfare of others. Over-delivery of insulin is a serious matter that poses catastrophic, lethal risks.

35. As a result of the defective MiniMed Infusion Sets, Randall Smith received a large quantity of insulin, which resulted in extreme hypoglycemia and loss of consciousness. Causes of action are hereby asserted for the injuries and damages sustained by Randall Smith.

CAUSES OF ACTION

COUNT I
PRODUCT LIABILITY

36. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

37. The Plaintiff hereby asserts a product liability claim pursuant to Section 6-5-521 of the Alabama Code, and other applicable Alabama law.

38. At all times relevant to the Complaint, the Defendants were in the business of designing, manufacturing, marketing, testing, labeling, selling and distributing Medtronic MiniMed Infusion Sets. The product at issue was defective and unreasonably dangerous at the

time it left the hands of the Defendants. Defendants placed their product into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design of the product.

39. Defendants' product was unreasonably and dangerously defective beyond the extent contemplated by ordinary users with ordinary knowledge regarding the product. Randall Smith was unaware of the danger as Defendants provided ineffective and inadequate warnings and instructions.

40. Defendants' product was defective due to inadequate post-marketing warnings and instructions, and/or inadequate testing and studies, and/or inadequate reporting regarding the results.

41. Defendants' product was defective in light of the dangers posed by its design and the likelihood of those avoidable dangers. Defendants' product was defective because the inherent risk of harm in Defendants' product design outweighed the utility or benefits of the existing product design. Defendants' product was defective because reasonably cost-effective and feasible state-of-the-art alternatives existed at the time that would not have undermined the product's usefulness.

42. Defendants were aware of effective substitutes for the product. The gravity and likelihood of the dangers posed by the product's design outweighed the feasibility, cost, and adverse consequences to the product's function of a safer alternative design that Defendants reasonably should have adopted.

43. There was a safer alternative design that would have prevented or significantly reduced the risk of injury. It was reasonable as well as economically and technologically feasible at the time the product left Defendants' control by the application of existing or

reasonably achievable scientific knowledge.

44. The defective and unreasonably dangerous conditions discussed herein existed when the product left Defendants' control. They existed when Defendants sold the product. They existed when Randall Smith received it.

45. At all relevant times, Defendants knew or reasonably should have known that their product was unreasonably dangerous and defective when used as designed and directed.

46. Defendants held themselves out as experts and specialists and therefore possessed a higher degree of skill and learning.

47. Defendants had a duty to exercise reasonable care, and to comply with the then existing standard of care, in the design, testing, research, development, packaging, distribution, promotion, marketing, advertising, instruction, and sale of their product. Specifically:

(a) Defendants had a continuing duty to ensure that the product they provided was safe and used correctly through proper design, testing, research, adequate instruction, post-market surveillance, and appropriate modifications;

(b) Defendants had a duty to anticipate the environment in which the product would be used and to design against the reasonably foreseeable risks attending the product's use in that setting, including misuse or alteration;

(c) Defendants had a continuing duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of their product;

(d) Defendants had a duty to provide adequate warnings and instructions, which means they had to be comprehensible to the average user, calculated to convey the material risks to the mind of a reasonably prudent person, and of an intensity commensurate with the danger involved;

(e) Defendants had a continuing duty to assure the product they provided was properly labeled and true to the representations Defendants made about it;

(f) Defendants had a continuing duty to make sure their product had complete and accurate information and instructions concerning its proper use;

(g) Defendants had a continuing duty to modify their products, and their packaging, instructions, promotional and advertising efforts to eliminate confusion and user error, assure compliance, and prevent harm; and

(h) Defendants had a continuing obligation to disseminate appropriate content and employ appropriate methods to convey accurate and complete product information.

48. In violation of the existing standards and duties of care, Defendants, individually and collectively, deviated from reasonable and safe practices in the following ways, by:

(a) designing a product defective in design and warnings/instructions;

(b) failing to conduct pre and post market safety tests and studies;

(c) failing to collect, analyze, and report available data regarding use of Defendants' product;

(d) failing to conduct adequate post-market monitoring and surveillance;

(e) failing to include adequate warnings about and/or instructions;

(f) failing to provide adequate warnings and/or proper instructions regarding proper uses of the product;

(g) failing to inform users that Defendants had not adequately tested or researched the product to determine its safety and risks;

(h) failing to educate and instruct users about the unique characteristics of their

product and the proper way to use it;

(i) failing to implement and execute corrective and preventive actions to eliminate injuries; and

(j) continuing to promote and market the product despite the foregoing failures.

49. Had Defendants designed a safe product and/or undertaken the tests, studies, and steps described herein, the injuries and damages complained of here would not have occurred.

50. The Defendants also breached express warranties. The Defendants represented and warranted to Randall Smith that its Medtronic MiniMed Infusion Sets were safe for use in accordance with the Defendants' protocols. Said representations were in the form of marketing materials, device information and product materials provided to Randall Smith. Randall Smith justifiably relied on said representations and express warranties in electing to use said product.

51. The Medtronic MiniMed Infusion Sets at issue did not conform to Defendants' express representations and warranties.

52. At all relevant times, said product did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

53. At all relevant times, said product did not perform in accordance with the Defendants' representations.

54. Defendants' product was not fit for the ordinary purpose for which such goods were used. It was unmerchantable when used as directed and defective in design, and the Defendants' failure to provide adequate warnings and instructions also resulted in said product being unreasonably dangerous. Defendants' product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Randall Smith.

55. The injuries and damages alleged herein were the reasonably foreseeable result of Defendants' product and conduct.

56. Defendants are bound for the care of their agents, servants, employees, officers, and directors and for the neglect and/or fraud of the same. Defendants are liable for the conduct of their agents, servants, employees, officers, and directors committed in the course of their activities on behalf of and in furtherance of the company. Defendants are liable for their agents, employees, officers, and directors conduct attempting to advance Defendants' business. Defendants expressly and impliedly authorized and ratified the conduct of their agents, servants, employees, officers, and directors. Defendants received significant benefits as a direct result of their agents', employees', servants', officers', and directors' conduct.

57. Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences. Defendants' wrongdoing constitutes gross negligence, and said gross negligence proximately caused the injuries and damages sustained by Randall Smith.

COMPENSATORY DAMAGES

58. Randall Smith suffered severe and permanent injuries and damages as a direct and proximate result of the conduct and breaches of the Defendants, as aforesaid, for which compensation is required. Specifically, the Defendants' products caused Randall Smith to sustain extreme hypoglycemia, resulting in loss of consciousness and the crashes at issue. The Plaintiff is seeking monetary damages from the Defendants to compensate the Plaintiff for damages arising from the defective Medtronic product, including all damages of any kind allowed by Alabama law.

59. As a result of the aforementioned acts and/or omissions, the Defendants are liable for all elements of damages including but not limited to:

(a) Damages for past doctor, hospital, drug, and medical bills;

(b) Damages for future doctor, hospital, drug, medical bills and life-care costs;

(c) Damages for loss of wages and wage earning capacity;

(d) Damages for disfigurement, impairment and disability;

(e) Damages for past mental anguish and emotional distress;

(f) Damages for physical pain and suffering;

(g) Damages for loss of enjoyment of life;

(h) Damages for all other losses, both economic and intrinsic, tangible and intangible, arising from the injuries as set out herein, all of which were proximately caused by the acts and/or omissions of the Defendants; and

(i) Any other relief which the Court or jury deems just or appropriate based upon the circumstances.

60. The Plaintiff reserves the right to prove the amount of damages at trial. The amount of compensatory damages will be in an amount to be determined by the jury.

PUNITIVE DAMAGES

61. As set forth herein above, Defendants' conduct exhibited gross negligence and a willful, wanton and reckless disregard for the safety of Randall Smith and others, constituting an independent tort. As a result of said conduct alleged herein, Defendants are liable for punitive damages and attorneys' fees, all litigation expenses and associated costs of litigation, pre-judgment interest and other damages pursuant to Alabama law.

62. The conduct justifying an award of punitive damages includes, but is not limited to, the Defendants' willful, malicious, intentional and gross negligence, the fraudulent and/or negligent acts of misrepresentation and/or concealment, as well as other conduct described herein. The amount of punitive damages to be awarded is an amount to be determined by the jury.

63. Plaintiff prays that punitive or exemplary damages be assessed against the Defendants in an amount sufficient to punish the Defendants for their wrongful conduct and to deter like conduct in the future, and to serve as an example and a warning to others, so as to deter others from engaging in a similar course of conduct and to encourage other companies to have due and proper regard for the rights and lives of consumers and patients, and to protect the general public from future wrongdoing, pursuant to Alabama law

WHEREFORE, PREMISES CONSIDERED, the Plaintiff, Randall Smith, sues and demands judgment from the Defendants, Medtronic MiniMed, Inc., MiniMed Distribution Corp., Medtronic, Inc., and Medtronic USA, Inc., and John Doe Defendants 1-5, and respectfully requests an order from this Court awarding damages and compensation for the following:

1. An award of actual, consequential and incidental damages in such amounts as are sufficient to compensate in full the Plaintiff for the losses and damages actually incurred as a result of the Defendants' defective product and wrongdoing;
2. An award of punitive damages in an amount adequate to punish the Defendants and serve as an example to deter similar conduct in the future;
3. An award of the Plaintiff's costs and expenses incurred in connection with this action, including attorneys' fees, expert witness fees and all other costs herein;
4. An award of pre-judgment and post-judgment interest as the Court deems appropriate; and
5. Granting such other and further relief as the Court deems just and proper, including restitution, imposition of a constructive trust and/or such extraordinary equitable or injunctive relief as permitted by law, equity or statutory provisions as the Court deems proper to prevent unjust enrichment of the Defendants and to provide the Plaintiff with an effective remedy for the damages caused and injuries suffered as a result of the Defendants' wrongdoing as aforesaid.

JURY TRIAL DEMANDED

Respectfully submitted, this the 27th day of December, 2018.

RANDALL SMITH

/s/ Ralph D. Gaines, III

RALPH D. GAINES, III, (GAI006)
AL Bar Number: ASB-6605-N69R
Attorney for Plaintiff Randall Smith
GAINES GAULT HENDRIX P.C.
3500 Blue Lake Drive, Suite 425
Birmingham, Alabama 35243
Telephone: 205-980-5888
Fax: 205-980-1098
Email: rgaines@ggh-law.com

Jason L. Nabors, Miss. Bar No. 101630 (*pro hac vice pending*)
NABORS LAW FIRM
P. O. Box 1334
Ridgeland, MS 39158
(662) 710-4979 (Telephone)
(601) 300-2975 (Fax)
jason@naborslawfirm.com